

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent of: Boschetti Confirmation No.: 1038
U.S. Patent No.: 7,591,993 Art Unit: 1618
Issued: September 22, 2009 Examiner: JONES, Dameron Levest
Application No.: 10/692,785
For: POLYVINYL ALCOHOL MICROSPHERES AND INJECTABLE SOLUTIONS OF THE SAME Attorney Docket No.: 9676-314-999 (CAM: 405916-999056)

**REQUEST FOR RECONSIDERATION OF
PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)**

MAIL STOP PETITION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Patentee hereby submits a second request for reconsideration of patent term adjustment for the above-identified patent, U.S. Patent No. 7,591,993 B2 (“the ’993 patent”), which was granted on Application No. 10/692,785 (“the ’785 application”). The United States Patent and Trademark Office (“PTO”) mailed a communication dated August 17, 2009, (“August 17th Communication,” Exhibit A), in which the PTO responded to Patentee’s request for reconsideration of patent term adjustment under 37 C.F.R. § 1.705(b), filed December 29, 2008 (“Request for Reconsideration of PTA under 37 C.F.R. § 1.705(b),” Exhibit B). In the August 17th Communication, the PTO stated that a decision on Patentee’s request under 37 C.F.R. § 1.705(b) was dismissed because “[r]equesting reconsideration of the patent term adjustment . . . based on the initial determination of patent term adjustment and a projected issuance date of the patent . . . is premature.” The August 17th Communication, page 1. The PTO also indicated that “applicant is advised that they may wait until the time of the issuance of the patent and file a request for reconsideration of the patent term adjustment pursuant to 37 CFR 1.705(d).” *Id.* The

PTO further indicated that “the Office will consider any request for reconsideration of the patent term adjustment due to an error in the calculation of 37 CFR 1.702(b) to be timely if the request for reconsideration is filed within two months of the issuance of the patent.”¹ *Id.*, at pages 1-2. The ‘993 patent issued September 22, 2009. Thus, the request for reconsideration is due on or before November 22, 2009. Because November 22, 2009 falls on a Sunday, the request for reconsideration period is extended to Monday, November 23, 2009, pursuant to 37 C.F.R. § 1.7. Thus, this request is timely filed.

The patent term adjustment under 35 U.S.C. § 154(b) indicated on the face of the ‘993 patent is 292 days. Patentee hereby respectfully requests reconsideration of the patent term adjustment under 35 U.S.C. § 154(b). Specifically, Patentee believes that the patent term adjustment of 292 days is not correct. The correct number of days for the patent term adjustment, for reasons explained below should be a total of 476 days. The factual and legal basis for this request is set forth below.

REMARKS

A request for reconsideration of patent term adjustment under 37 C.F.R. § 1.705(d) must comply with the requirements of 37 C.F.R. § 1.705(b), which provides that a request for reconsideration of patent term adjustment must be accompanied by:

- (1) the fee set forth in 37 C.F.R. § 1.18(e); and
- (2) a statement of the facts involved, specifying:
 - (i) the correct patent term adjustment and the basis or bases under 37C.F.R. § 1.702 for the adjustment;

¹ Patentee submits that a request for reconsideration of patent term adjustment due to errors in the calculation of 37 C.F.R §§ 1.702(a)(1) and 1.702(b) delay was filed on December 29, 2008, the same day as the issue fee payment. *See* Request for Reconsideration of PTA under 37 C.F.R. § 1.705(b), Exhibit B. Thus, pursuant to 37 C.F.R § 1.705(b) and 35 U.S.C. § 154(b), Patentee submits that the issues raised under 37 C.F.R § 1.702(a)(1) were timely filed.

- (ii) the relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) to which the patent is entitled;
- (iii) whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer; and
- (iv)(A) any circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704; or
- (B) that there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704.

In support of this request, Patentee submits the fee and the following statement of facts and law:

1. **Fee Required Under 37 C.F.R. § 1.705(b)(1)**

Pursuant to 37 C.F.R. §§ 1.705(b)(1) and § 1.18(e), the fee required for filing this application is believed to be **\$200.00** and will be paid by EFS-web.

Please charge any underpayment or credit any overpayment to Jones Day Deposit Account No. 50-3013 (Ref. No. 9676-314-999).

2. **Statement Required Under 37 C.F.R. § 1.705(b)(2)**

Pursuant to 37 C.F.R. § 1.702, Patentee submits the following statement of facts in support of this application:

- (i) The correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment are as follows:

1. Correct patent term adjustment:

The correct patent term adjustment is 476 days, which is attributable to (a) the failure of the PTO to take certain actions within specified time frames (a delay under 37 C.F.R. § 1.702(a); “the A period”); and (b) the failure of the PTO to issue a patent within three years of the actual filing date of the ’785 application (a delay under 37 C.F.R. § 1.702(b); the “B period”).

2. Bases under 37 C.F.R. § 1.702 for the adjustment:

- (a) *PTO Delay under 37 C.F.R. § 1.702(a) - Failure to Take Specific Action Within Specified Time Frames (the “A Period”)*

The delay by the PTO under 37 C.F.R. § 1.702(a) is believed to be 330 days.

Pursuant to 37 C.F.R. § 1.703(a), the period of adjustment under § 1.702(a) (the “A period”) is the sum of specified periods, which include, among other things, the number of days in the period beginning on the day after the date that is fourteen months after the date on which the application was filed and ending on the mailing of an action under 35 U.S.C. § 132, as specified in 37 C.F.R. § 1.703(a)(1), and the number of days in the period beginning on the day after the date that is four months after the date the issue fee was paid and all outstanding requirements were satisfied and ending on the date a patent was issued, as specified in 37 C.F.R. § 1.703(a)(6).

As acknowledged by the PTO in its calculation of the patent term adjustment, the PTO failed to mail a notification under 35 U.S.C. § 132 within fourteen months from the date of filing of the ’785 application. See PTO’s Patent Application Information Retrieval page for U.S. Application No. 10/692,785 at Patent Term Adjustment History (“PTO PAIR Adjustment,” Exhibit C). The ’785 application was filed on October 27, 2003. The first notification under 35 U.S.C. § 132 (a Restriction Requirement) was mailed by the PTO on June 29, 2005.

Accordingly, the PTO did not mail a notification under 35 U.S.C. § 132 (or a notice of allowance under 35 U.S.C. § 151) within fourteen months after the date on which the application was filed (or by December 27, 2004), and thus, the delay under 37 C.F.R. § 1.702(a)(1) is believed to be 184 days.

In addition, the PTO acknowledges in its calculation of the patent term adjustment that the PTO failed to issue a patent within four months after the issue fee was paid and all outstanding requirements were satisfied. *See* PTO PAIR Adjustment, Exhibit C. As indicated in the PTO PAIR Adjustment, the issue payment for the '785 application was received and verified on December 29, 2008. However, the patent was not issued until September 22, 2009. Accordingly, the PTO did not issue a patent within four months after the date on which the issue fee was paid under 35 U.S.C. § 151 and thus, the delay under 37 C.F.R. § 1.702(a)(4) is believed to be 146 days.

Accordingly, the delay under 37 C.F.R. § 1.702(a) is the sum of 184 days and 146 days, which is equal to 330 days.

(b) *PTO Delay under 37 C.F.R. § 1.702(b) - Failure to Issue a Patent Within Three Years of the Actual Filing Date of the Application (the "B period")*

The delay by the PTO under 37 C.F.R. § 1.702(b) is believed to be 369 days.²

Pursuant to 37 C.F.R. § 1.703(b), the period of adjustment under § 1.702(b) (the "B period") is equal to the period beginning the day after the date that is three years after the date on which the application was filed and ending the date a patent was issued, but not including the sum of the number of days in the period beginning on the date on which a request for continued examination of the application was filed and ending on the date the patent was issued.

² Patentee submits that due to a typographical error, the delay by the PTO under 37 C.F.R. § 1.702(b) was inadvertently stated as 368 days in the Request for Reconsideration of PTA under 37 C.F.R. § 1.705(b) filed December 29, 2008.

The '785 application was filed under on October 27, 2003. The PTO did not issue a patent within three years of the date on which the application was filed, *i.e.*, by October 27, 2006.

A Request for Continued Examination was filed on October 31, 2007. Thus, the entire period between October 31, 2007 and the issuance of the patent on the above-referenced patent application is excluded from Patent Term Adjustment calculations. See 37 C.F.R. § 1.702(b)(1).

Accordingly, Patentee submits that the period of delay in the B period is 369 days, which is the number of days between the three year anniversary of October 27, 2006 and the date of the filing of the Request for Continued Examination on October 31, 2007.

(c) Overlapping Days in the PTO Delay Periods

The period of overlap between the delays by the PTO under 37 C.F.R. §§ 1.702(a) and (b) is 0 days.

According to 35 U.S.C. § 154(b)(2)(A): “To the extent that periods of delay attributable to grounds specified in paragraph (1) *overlap*, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.” See 35 U.S.C. § 154(b)(2)(A).

Patentee respectfully submits that under recent case law, calculating the patent term adjustment is the result of summing the number of days of delay under 37 C.F.R. § 1.702(a) that do not comprise actual calendar days occurring in the B period (that is, the A period minus calendar days overlapping in both the A and B periods) and the number of days of delay under 37 C.F.R. § 1.702(b) (the B period). See *Wyeth et al. v. Dudas*, 2008 WL 445642, 88 USPQ2d 1538 (D.D.C. 2008).

In *Wyeth*, the Court held that “the only way that periods of time can ‘overlap’ is if they occur on the same day [and thus, if] an ‘A delay’ occurs on one calendar day and a ‘B delay’ occurs on another, they do not overlap.”

As discussed above, Patentee submits that there are zero (0) actual calendar days of the 330 days in the A period that were actual calendar days included in the 369 days of the B period. That is, the 184 actual calendar days of delay under 37 C.F.R. § 1.702(a)(1) or the 146 actual calendar days of delay under 37 C.F.R. § 1.702(a)(4) do not overlap any of the 369 actual calendar days of delay under 37 C.F.R. § 1.702(b). As such, Patentee believes that the patent term adjustment of 185 days (369 minus 184), described as “PTA 36 Months” in the PTO PAIR Adjustment, is not correct.

- (ii) The relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) are as follows:

- 1. Adjustment under 37 C.F.R. §§ 1.703(a) through (e):

An adjustment is sought under 37 C.F.R. § 1.703(a)(1), which provides, in relevant part, that the period of adjustment is “[t]he number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. § 111(a) and ending on the date of mailing of either an action under 35 U.S.C. § 132, or a notice of allowance under 35 U.S.C. § 151, whichever occurs first.”

The patent term adjustment calculated by the PTO correctly included the time period under 37 C.F.R. § 1.702(a)(1) for the period beginning December 27, 2004 (fourteen months after the date on which the ’785 application was filed) and ending on June 29, 2005, the date the Restriction Requirement was mailed from the PTO. Patentee confirms this period consists of 184 days.

An adjustment is also sought under 37 C.F.R. § 1.703(a)(6), which provides, in relevant part, that the period of adjustment is “[t]he number of days, if any, in the period beginning on the day after the date that is four months after the date the issue fee was paid and all outstanding requirements were satisfied and ending on the date a patent was issued.”

The patent term adjustment calculated by the PTO correctly included the time period under 37 C.F.R. § 1.702(a)(4) for the period beginning April 29, 2009 (four months after the date on which the issue fee for the '785 application was paid) and ending on September 22, 2009, the date the patent was issued. Patentee confirms this period consists of 146 days.

An adjustment is further sought under 37 C.F.R. § 1.703(b), which provides, in relevant part, that “the period of adjustment under 37 C.F.R. § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. § 111(a)...and ending on the date a patent was issued.” A Request for Continued Examination was filed on October 31, 2007. Thus, pursuant to 37 C.F.R. § 1.702(b)(1) and 37 C.F.R. § 1.703(b)(1), the entire period between October 31, 2007 and the issuance of the patent on the above-referenced patent application is excluded from Patent Term Adjustment calculations. However, an adjustment is sought under 37 C.F.R. § 1.703(b) of 369 days, which is the number of days between the three year anniversary of October 27, 2006 and the date of the filing of the Request for Continued Examination on October 31, 2007.

Patentee further submits that the 184 actual calendar days of delay under 37 C.F.R. § 1.702(a)(1) or the 146 actual calendar days of delay under 37 C.F.R. § 1.702(a)(4) do not overlap any of the 369 actual calendar days of delay under 37 C.F.R. § 1.702(b), as explained above. As such, Patentee believes that the patent term adjustment of 185 days (369 minus 184), described as “PTA 36 Months” in the PTO PAIR Adjustment, is not correct.

Accordingly, Patentee’s believe that the delays attributable to the PTO under 37 C.F.R. § 1.702 are 699 days, not 515 days as calculated by the PTO.

2. Adjustment under 37 C.F.R. § 1.703(f):

As discussed in sections (i) and (ii) above, Patentee believes that the total delays by the PTO amount to 699 days under 37 C.F.R. § 1.702(a)(1) (*i.e.*, 184 days), 37 C.F.R. § 1.702(a)(4) (*i.e.*, 146 days) and § 1.702(b) (*i.e.*, 369 days).

As discussed in Section (iv) below, Patentee further believes that the total delays attributable to Patentee are 223 days.


As such, Patentee believes that the total period of adjustment due under 37 C.F.R. § 1.703(f) is 476 days, which is the sum of the periods by the PTO delay calculated under 37 C.F.R. §§ 1.702(a) through (e) (*i.e.*, 699 days) to the extent that such periods are not overlapping, less the sum of the periods calculated under 37 C.F.R. § 1.704 (*i.e.*, 223 days).

- (iii) The '785 application is not subject to a terminal disclaimer.
- (iv) The circumstances during the prosecution of the '785 application that might constitute a failure to engage in reasonable efforts to conclude processing or examination of the '785 application as set forth in 37 C.F.R. § 1.704 are believed to consist of 223 days. Patentee confirms that the total delays attributable to Patentee are 223 days, as calculated by the PTO. *See* PTO PAIR Adjustment, Exhibit C.

In summary, the total adjustment under 37 C.F.R. § 1.702(a) and (b) is 699 days, the total delays attributable to Patentee under 37 C.F.R. § 1.704 are 223 days, and thus the total period of adjustment due under 37 C.F.R. § 1.703(f) is believed to be 476 days. Accordingly, Patentee respectfully requests an adjustment of patent term under 37 C.F.R. § 1.703(f) totaling 476 days.

Date: Nov. 23, 2009

Respectfully submitted,


For: Tamera M. Weiss 47,856
(Reg. No.)
For: Anthony M. Insogna (Reg. No. 35,203)

JONES DAY
222 East 41st Street
New York, New York 10017
(212) 326-3939

U.S. Patent No. 7,591,993
Request for Reconsideration of
Patent Term Adjustment Under 37 C.F.R. § 1.705(d)
November 23, 2009
Exhibit A

EXHIBIT A:
August 17th Communication



UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application

Boschetti

Application No. 10/692,785

Filed: October 27, 2003

Dkt. No.: 9676-314-999

OFFICE OF PETITIONS

PATENT TERM ADJUSTMENT

This decision is in response to the "REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(b)," filed December 29, 2008.

Applicants submit that the correct patent term adjustment to be indicated on the patent is 387 days, not zero days as calculated by the Office as of the mailing of the initial determination of patent term adjustment. Applicant requests this correction on the basis that the Office will take in excess of three years to issue this patent and also on the basis that the total applicant delay is 165.

As the instant application for patent term adjustment requests reconsideration of the patent term adjustment as it relates to the Office's failure to issue the patent within 3 years of the filing date, the application for patent term adjustment under 37 CFR 1.705(b) is DISMISSED as PREMATURE.

Knowledge of the actual date the patent issues is required to calculate the amount, if any, of additional patent term patentee is entitled to for Office failure to issue the patent within 3 years. See, § 1.702(b). (This is true even where a request for continued examination (RCE) was filed). The computer will not undertake the § 1.702(b) calculation until the actual date of issuance of the patent has been determined. Likewise, the computer will not calculate any further Office delay under § 1.702(a)(4) or applicant delay under § 1.704(c)(10) until the actual date of issuance of the patent has been determined. As such, the Office can not make a determination on the correctness of the patent term adjustment until the patent has issued.

Requesting reconsideration of the patent term adjustment to be indicated on the patent under 37 CFR 1.705(b) based on the initial determination of patent term adjustment and a projected issuance date of the patent (or even the filing date of the request for continued examination) is premature. Accordingly, it is appropriate to dismiss as premature such a request.

Rather than file an application for patent term adjustment under 37 CFR 1.705(b) contesting the 37 CFR 1.702(b) calculation at the time of the mailing of the notice of allowance, applicant is advised that they may wait until the time of the issuance of the patent and file a request for reconsideration of the patent term adjustment pursuant to 37 CFR 1.705(d). As the USPTO does not calculate the amount of time earned pursuant to 37 CFR 1.702(b) until the time of the issuance of the patent, the Office will consider any request for reconsideration of the patent term adjustment due to an error in the calculation of 37 CFR 1.702(b) to be timely if the request for reconsideration is filed within two

months of the issuance of the patent. However, as to all other bases for contesting the initial determination of patent term adjustment received with the notice of allowance, applicant must timely file an application for patent term adjustment prior to the payment of the issue fee¹.

Applicant acknowledges an applicant delay 165 days. The reduction of 165 days is reflected in the determination of patent term adjustment. However, the adjustment is further reduction 33 days in accordance with 37 CFR 1.704(b) in connection with the response to non-final Office action filed May 27, 2008. The reduction commenced April 25, 2008, the day after the date that is three months after the date that the non-final Office action was mailed, and ended May 27, 2008, the date that the reply thereto was filed.

In view thereof, as of the time of allowance, the application is entitled to an overall adjustment of zero days, as reflected in the determination of patent term adjustment (adjustment of 184 days less reductions of 198 days).

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e) for consideration of the application for patent term adjustment under 37 CFR 1.705(b).

Any request for reconsideration of the patent term adjustment indicated on the patent must be timely filed within 2 months after issuance pursuant to 37 CFR 1.705(d) and must include payment of the required fee under 37 CFR 1.18(e).

The Office of Data Management has been advised of this decision. This application is being referred to the Office of Data Management for issuance of the patent.

Telephone inquiries specific to this decision should be directed to the undersigned at (571) 272-3205.



Alesia M. Brown
Petitions Attorney
Office of Petitions

¹ For example, if applicant disputes both the calculation of patent term adjustment under 37 CFR 1.702(a)(1) for Office failure to mail a first Office action or notice of allowance not later than fourteen months after the date on which the application was filed and under 37 CFR 1.702(b) for Office failure to issue a patent within three years of the actual filing date of the application, then applicant must still timely file an application for patent term adjustment prior to the payment of the issue fee to contest the calculation of Office delay in issuing a first Office action or notice of allowance. See 37 CFR 1.705(b) and 35 U.S.C. 154(b)(3)(B). A dispute as to the calculation of the §1.702(a)(1) period raised on request for reconsideration of patent term adjustment under 37 CFR 1.705(d) will be dismissed as untimely filed.

U.S. Patent No. 7,591,993
Request for Reconsideration of
Patent Term Adjustment Under 37 C.F.R. § 1.705(d)
November 23, 2009
Exhibit B

EXHIBIT B:
Request for Reconsideration of PTA under 37 C.F.R. § 1.705(b)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Boschetti	Confirmation No.:	1038
Application. No.:	10/692,785	Art Unit:	1618
Filed:	October 27, 2003	Examiner:	JONES, Dameron Levest
For:	POLYVINYL ALCOHOL MICROSPHERES AND INJECTABLE SOLUTIONS OF THE SAME	Attorney Docket No.:	9676-314-999 (CAM: 405916-999056)

**REQUEST FOR RECONSIDERATION OF
PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(b)**

MAIL STOP: ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants received a Notice of Allowance mailed September 29, 2008, from the United States Patent and Trademark Office ("PTO") in connection with Application No. 10/692,785 (hereinafter "the '785 application"), together with a Determination of Patent Term Adjustment under 35 U.S.C. §154(b) stating that the projected patent term adjustment to date is 0 days.

Applicants hereby respectfully request reconsideration of the patent term adjustment indicated in the Determination of Patent Term Adjustment under 35 U.S.C. §154(b) ("Determination") mailed September 29, 2008. Specifically, Applicants believe that the patent term adjustment of 0 days is not correct. The correct number of days for the patent term adjustment, for reasons explained below, is instead believed to be 387 days. The factual and legal basis for this request is set forth below.

COPY

REMARKS

A request for reconsideration of patent term adjustment under 37 C.F.R. § 1.705(b) must be accompanied by:

- (1) the fee set forth in 37 C.F.R. § 1.18(e); and
- (2) a statement of the facts involved, specifying:
 - (i) the correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment;
 - (ii) the relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) to which the patent is entitled;
 - (iii) whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer; and
 - (iv)(A) any circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704; or
 - (B) that there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704.

See 37 C.F.R. § 1.705(b).

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In support of this request, Applicants submit the fee and the following statement of facts and law:

1. Fee Required Under 37 C.F.R. § 1.705(b)(1)

Pursuant to 37 C.F.R. §§ 1.705(b)(1) and § 1.18(e), the fee required for filing this application is believed to be **\$200.00** and will be paid by EFS-web.

Please charge any underpayment or credit any overpayment to Jones Day Deposit Account No. 50-3013 (Ref. No. 9676-314-999).

2. Statement Required Under 37 C.F.R. § 1.705(b)(2)

Pursuant to 37 C.F.R. § 1.702, Applicants submit the following statement of facts in support of this application:

- (i) The correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment are as follows:

1. Correct patent term adjustment:

The correct patent term adjustment is **387** days, which is attributable to (a) the failure of the PTO to mail a notification under 35 U.S.C. § 132 not later than fourteen months after the date on which the '785 application was filed under 35 U.S.C. § 111(a) (a delay under 37 C.F.R. § 1.702(a)(1); "the A period"); and (b) the failure of the PTO to issue a patent within three years of the actual filing date of the '785 application (a delay under 37 C.F.R. § 1.702(b); the "B period").

2. Bases under 37 C.F.R. § 1.702 for the adjustment:

- (a) PTO Delay under 37 C.F.R. § 1.702(a) - Failure to Take Specific Action Within Specified Time Frames (the "A Period")

The delay by the PTO under 37 C.F.R. § 1.702(a) is believed to be **184** days.

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Pursuant to 37 C.F.R. § 1.703(a), the period of adjustment under § 1.702(a) (the "A period") is equal to the number of days in the period beginning on the day after the date that is fourteen months after the date on which the application was filed and ending on the mailing of an action under 35 U.S.C. § 132.

As acknowledged by the PTO in its calculation of the patent term adjustment, the PTO failed to mail a notification under 35 U.S.C. §132 within fourteen months from the date of filing of the '785 application. See PTO's Patent Application Information Retrieval page for U.S. Application No. 10/692,785 at Patent Term Adjustment History ("PTO PAIR Adjustment," Exhibit A). The '785 application was filed on October 27, 2003. The first notification under 35 U.S.C. §132 (a Restriction Requirement) was mailed by the PTO on June 29, 2005. Accordingly, the PTO did not mail a notification under 35 U.S.C. §132 (or a notice of allowance under 35 U.S.C. §151) within fourteen months after the date on which the application was filed (or by December 27, 2004), and thus, the delay under 37 C.F.R. § 1.702(a)(1) is believed to be 184 days.

(b) *PTO Delay under 37 C.F.R. § 1.702(b) - Failure to Issue a Patent Within Three Years of the Actual Filing Date of the Application (the "B period")*

The delay by the PTO under 37 C.F.R. § 1.702(b) is believed to be 368 days.

Pursuant to 37 C.F.R. § 1.703(b), the period of adjustment under § 1.702(b) (the "B period") is equal to the period beginning the day after the date that is three years after the date on which the application was filed and ending the date a patent was issued, but not including the sum of the number of days in the period beginning on the date on which a request for continued examination of the application was filed and ending on the date the patent was issued.

The '785 application was filed under on October 27, 2003. The PTO did not issue a patent within three years of the date on which the application was filed, *i.e.*, by October 27, 2006.

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A Request for Continued Examination was filed on October 31, 2007. Thus, the entire period between October 31, 2007 and the issuance of the patent on the above-referenced patent application is excluded from Patent Term Adjustment calculations. See 37 C.F.R. § 1.702(b)(2).

Accordingly, Applicants submit that the period of delay in the B period is 368 days, which is the number of days between the three year anniversary of October 27, 2006 and the date of the filing of the Request for Continued Examination on October 31, 2007.

(c) Overlapping Days in the PTO Delay Periods

The period of overlap between the delay by the PTO under 37 C.F.R. §§ 1.702(a) and (b) is 0 days.

According to 35 U.S.C. § 154(b)(2)(A): “To the extent that periods of delay attributable to grounds specified in paragraph (1) *overlap*, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.” See 35 U.S.C. § 154(b)(2)(A).

Applicants respectfully submit that under recent case law, calculating the patent term adjustment is the result of summing the number of days of delay under 37 C.F.R. § 1.702(a) that do not comprise actual calendar days occurring in the B period (that is, the A period minus calendar days overlapping in both the A and B periods) and the number of days of delay under 37 C.F.R. § 1.702(b) (the B period). See *Wyeth et al. v. Dudas*, 2008 WL 445642, 88 USPQ2d 1538 (D.D.C. 2008).

In *Wyeth*, the Court held that “the only way that periods of time can ‘overlap’ is if they occur on the same day [and thus, if] an ‘A delay’ occurs on one calendar day and a ‘B delay’ occurs on another, they do not overlap.”

As discussed above, Applicants submit that there are zero (0) actual calendar days of the 184 days in the A period that were actual calendar days included in the 368 days of the B period.

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- (ii) The relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) are as follows:

1. Adjustment under 37 C.F.R. §§ 1.703(a) through (e):

An adjustment is sought under 37 C.F.R. § 1.703(a)(1), which provides, in relevant part, that the period of adjustment is “[t]he number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. § 111(a) and ending on the date of mailing of either an action under 35 U.S.C. §132, or a notice of allowance under 35 U.S.C. §151, whichever occurs first.”

The patent term adjustment calculated by the PTO correctly included the time period under 37 C.F.R. § 1.702(a)(1) for the period beginning December 27, 2004 (fourteen months after the date on which the ‘785 application was filed) and ending on June 29, 2005, the date the Restriction Requirement was mailed from the PTO. Applicants confirm this period consists of 184 days.

An adjustment is also sought under 37 C.F.R. § 1.703(b), which provides, in relevant part, that “the period of adjustment under 37 C.F.R. § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a)...and ending on the date a patent was issued.” A Request for Continued Examination was filed on October 31, 2007. Thus, pursuant to 37 C.F.R. § 1.702(b)(2) and 37 C.F.R. § 1.703(b)(1), the entire period between October 31, 2007 and the issuance of the patent on the above-referenced patent application is excluded from Patent Term Adjustment calculations. However, an adjustment is sought under 37 C.F.R. § 1.703(b) of 368 days, which is the number of days between the three year anniversary of October 27, 2006 and the date of the filing of the Request for Continued Examination on October 31, 2007.

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Applicants further submit that the 184 actual calendar days of delay under 37 C.F.R. § 1.702(a) do not overlap the any of the 368 actual calendar days of delay under 37 C.F.R. § 1.702(b), as explained above.

Accordingly, Applicants' believe that the delays attributable to the PTO under 37 C.F.R. § 1.702 total 552 days, not 184 days as calculated by the PTO.

2. Adjustment under 37 C.F.R. § 1.703(f):

As discussed in sections (I) and (ii) above, Applicants believe that the total delay by the PTO amounts to 552 days under 37 C.F.R. § 1.702(a)(1) (*i.e.*, 184 days) and § 1.702(b) (*i.e.*, 368 days).

As discussed in Section (iv) below, Applicants further believe that the total delay attributable to Applicants is 165 days.

As such, Applicants believe that the total period of adjustment due under 37 C.F.R. § 1.703(f) is 387 days, which is the sum of the periods by the PTO calculated under 37 C.F.R. §§ 1.702(a) through (e) (*i.e.*, 552 days) to the extent that such periods are not overlapping, less the sum of the periods calculated under § 1.704 (*i.e.*, 165 days).

- (iii) The '785 application is not subject to a terminal disclaimer.
- (iv) The circumstances during the prosecution of the '785 application that might constitute a failure to engage in reasonable efforts to conclude processing or examination of the '785 application as set forth in 37 C.F.R. § 1.704 are believed to consist of the following:

As acknowledged by the PTO in its calculation of the patent term adjustment, Applicants have a cumulative total of 165 days of Applicant delay through October 31, 2007 (RCE filing), which includes a total of 75 days of delay prior to October 27, 2006 (the 3 year anniversary) and

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a total of 90 days between October 27, 2006 and October 31, 2007. *See* PTO PAIR Adjustment, Exhibit A.¹

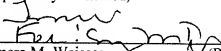
As such, Applicants believe that the delay by the Applicants under 37 C.F.R. § 1.704(a) is 165 days.

In summary, the total adjustment under 37 C.F.R. § 1.702(a) and (b) is 552 days, the total delays attributable to Applicants under 37 C.F.R. § 1.704 is 165 days, and thus the total period of adjustment due under 37 C.F.R. § 1.703(f) is believed to be 387 days. Accordingly, Applicants respectfully request an adjustment of patent term under 37 C.F.R. § 1.703(f) totaling 387 days.

Applicants submit that the issues raised in this request for reconsideration of patent term adjustment are timely raised under 37 C.F.R. § 1.705(b), which provides in relevant part, that “[a]n application for patent term adjustment under this section *must be filed no later than the payment of the issue fee...*” (emphasis added); *e.g.*, three (3) months from the mailing of the Notice of Allowance. An Issue Fee Payment Authorization accompanies this Request, hence Applicants submit that the issues raised in this request are timely raised.

Respectfully submitted,

Date: December 29, 2008


Tamera M. Weissner (Reg. No.) 47,856
For: Anthony M. Insogna (Reg. No. 35,203)

JONES DAY
222 East 41st Street
New York, New York 10017
(212) 326-3939

¹ Applicants have a further 76 days after October 31, 2007, which includes 33 days of delay shown in the PTO PAIR Adjustment, plus an additional 43 days for the number of days between September 29, 2008 Notice of Allowance and November 10, 2008 Response to Amendment under § 1.312. However, because this delay is after the filing of an RCE on October 31, 2007, the entire period of which is excluded from calculation of patent term pursuant to 37 C.F.R. § 1.703(b), only delays occurring before October 31, 2007 are discussed herein with respect to the overall calculation of patent term.

Application No. 10/692,785
Request for Reconsideration of
Patent Term Adjustment Under 37 C.F.R. § 1.705(b)
December 29, 2008
Exhibit A

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EXHIBIT A:
PTO PAIR Adjustment

10/692,785

POLYVINYL ALCOHOL MICROSPHERES, AND INJECTABLE SOLUTIONS OF THE SAME

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COPY**Patent Term Adjustments**

Patent Term Adjustment (PTA) for Application Number: 10/692,785

Filing or 371(c) Date:	10-27-2003	USPTO Delay (PTO) Delay (days):	184
Issue Date of Patent:	-	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	198
Post-Issue Petitions (days):	+0	Total PTA (days):	0
USPTO Adjustment(days):	+0	Explanation Of Calculations	

Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
09-29-2008	Mail Notice of Allowance		
09-25-2008	Notice of Allowance Data Verification Completed		
09-25-2008	Case Docketed to Examiner in GAU		
09-25-2008	Document Verification		
09-25-2008	Examiner's Amendment Communication		
09-15-2008	Examiner Interview Summary Record (PTOL - 413)		
09-25-2008	Date Forwarded to Examiner		
09-15-2008	Response after Non-Final Action		
09-04-2008	Mail Non-Final Rejection		
09-02-2008	Non-Final Rejection		
05-27-2008	Information Disclosure Statement considered		
05-27-2008	Information Disclosure Statement (IDS) Filed		
06-26-2008	Date Forwarded to Examiner		
05-27-2008	Response after Non-Final Action		33
05-27-2008	Request for Extension of Time - Granted		↑
05-27-2008	Information Disclosure Statement (IDS) Filed		↑
01-24-2008	Mail Non-Final Rejection		↑
01-22-2008	Non-Final Rejection		
10-31-2007	Information Disclosure Statement considered		
10-31-2007	Information Disclosure Statement (IDS) Filed		
12-06-2007	Date Forwarded to Examiner		
12-06-2007	Date Forwarded to Examiner		
10-31-2007	Request for Continued Examination (RCE)		19
12-06-2007	DISPOSAL FOR A RCE/CPA/129 (express abandonment if CPA)		↑
10-31-2007	Request for Extension of Time - Granted		↑
10-31-2007	Information Disclosure Statement (IDS) Filed		↑
10-31-2007	Workflow - Request for RCE - Begin		↑
07-12-2007	Mail Final Rejection (PTOL - 326)		↑
07-09-2007	Final Rejection		
04-11-2007	Information Disclosure Statement considered		
11-07-2006	Information Disclosure Statement considered		
04-11-2007	Information Disclosure Statement (IDS) Filed		
04-11-2007	Information Disclosure Statement (IDS) Filed		

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05-02-2007	Date Forwarded to Examiner	
04-11-2007	Response after Non-Final Action	
04-11-2007	Request for Extension of Time - Granted	71
11-21-2006	Mail Examiner Interview Summary (PTOL - 413)	↑
11-07-2006	Information Disclosure Statement (IDS) Filed	↑
11-07-2006	Information Disclosure Statement (IDS) Filed	↑
11-14-2006	Examiner Interview Summary Record (PTOL - 413)	↑
10-30-2006	Mail Non-Final Rejection	↑
10-27-2006	Non-Final Rejection	
10-12-2006	Correspondence Address Change	
10-13-2006	Change in Power of Attorney (May Include Associate POA)	
10-12-2006	Date Forwarded to Examiner	
10-02-2006	Amendment after Final Rejection	30
10-02-2006	Request for Extension of Time - Granted	↑
06-02-2006	Mail Final Rejection (PTOL - 326)	↑
05-30-2006	Final Rejection	
03-27-2006	Date Forwarded to Examiner	
03-16-2006	Response after Non-Final Action	28
03-16-2006	Request for Extension of Time - Granted	↑
11-16-2005	Mail Non-Final Rejection	↑
11-14-2005	Non-Final Rejection	
09-15-2005	Information Disclosure Statement considered	
08-29-2005	Information Disclosure Statement considered	
03-07-2005	Information Disclosure Statement considered	
10-27-2003	Information Disclosure Statement considered	
09-15-2005	Reference capture on IDS	
09-15-2005	Information Disclosure Statement (IDS) Filed	17
09-15-2005	Information Disclosure Statement (IDS) Filed	
08-29-2005	Information Disclosure Statement (IDS) Filed	↑
08-29-2005	Information Disclosure Statement (IDS) Filed	↑
09-07-2005	Date Forwarded to Examiner	↑
08-29-2005	Response to Election / Restriction Filed	↑
08-29-2005	Request for Extension of Time - Granted	
06-29-2005	Mail Restriction Requirement	184
06-27-2005	Requirement for Restriction / Election	↑
04-05-2005	Case Docketed to Examiner in GAU	↑
03-07-2005	Reference capture on IDS	↑
03-07-2005	Information Disclosure Statement (IDS) Filed	↑
03-07-2005	Information Disclosure Statement (IDS) Filed	↑
10-27-2003	Reference capture on IDS	↑
10-19-2004	IFW TSS Processing by Tech Center Complete	↑
10-27-2003	Information Disclosure Statement (IDS) Filed	↑
10-27-2003	Information Disclosure Statement (IDS) Filed	↑
10-19-2004	Case Docketed to Examiner in GAU	↑

02-05-2004	Application Return from OIPE	↑
02-05-2004	Application Return TO OIPE	↑
02-05-2004	Application Is Now Complete	↑
02-03-2004	Application Dispatched from OIPE	↑
02-04-2004	Application Is Now Complete	↑
01-28-2004	Cleared by L&R (LARS)	↑
01-20-2004	Referred to Level 2 (LARS) by OIPE CSR	↑
12-10-2003	IFW Scan & PACR Auto Security Review	↑
10-27-2003	Initial Exam Team nn	↑

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U.S. Patent No. 7,591,993
Request for Reconsideration of
Patent Term Adjustment Under 37 C.F.R. § 1.705(d)
November 23, 2009
Exhibit C

EXHIBIT C:
PTO PAIR Adjustment

10/692,785	POLYVINYL ALCOHOL MICROSPHERES, AND INJECTABLE SOLUTIONS OF THE SAME	11-23-2009::00:04:59
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Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 10/692,785

Filing or 371(c) Date:	10-27-2003	USPTO Delay (PTO) Delay (days):	515
Issue Date of Patent:	09-22-2009	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	223
Post-Issue Petitions (days):	+0	Total PTA (days):	292
USPTO Adjustment(days):	+0	Explanation Of Calculations	

Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
09-02-2009	PTA 36 Months	185	
09-22-2009	Patent Issue Date Used in PTA Calculation	146	
08-21-2009	Dispatch to FDC	↑	
08-17-2009	Mail-Petition Decision - Dismissed	↑	
08-17-2009	Petition Decision - Dismissed	↑	
12-29-2008	Petition Entered	↑	
12-31-2008	Application Is Considered Ready for Issue	↑	
12-29-2008	Issue Fee Payment Verified	↑	
12-29-2008	Statement Filed Indicating a Loss of Entitlement to Small Entity Status		
12-29-2008	Issue Fee Payment Received		
11-10-2008	Mail Response to 312 Amendment (PTO-271)		
11-07-2008	Response to Amendment under Rule 312		
10-17-2008	Amendment after Notice of Allowance (Rule 312)		25
11-03-2008	Pubs Case Remand to TC		
10-28-2008	Mail PUB Notice of non-compliant IDS		
10-28-2008	PUB Notice of non-compliant IDS		
10-17-2008	Information Disclosure Statement considered		
10-28-2008	Filing Receipt - Corrected		
10-17-2008	Information Disclosure Statement (IDS) Filed		
09-29-2008	Mail Notice of Allowance		
09-25-2008	Notice of Allowance Data Verification Completed		
09-25-2008	Case Docketed to Examiner in GAU		
09-25-2008	Document Verification		
09-25-2008	Examiner's Amendment Communication		
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05-27-2008	Request for Extension of Time - Granted	⬆
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07-12-2007	Mail Final Rejection (PTOL - 326)	⬆
07-09-2007	Final Rejection	
04-11-2007	Information Disclosure Statement considered	
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04-11-2007	Information Disclosure Statement (IDS) Filed	
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02-05-2004	Application Is Now Complete		↑
02-03-2004	Application Dispatched from OIPE		↑
02-04-2004	Application Is Now Complete		↑
01-28-2004	Cleared by L&R (LARS)		↑
01-20-2004	Referred to Level 2 (LARS) by OIPE CSR		↑
12-10-2003	IFW Scan & PACR Auto Security Review		↑
10-27-2003	Initial Exam Team nn		↑

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